Supreme Court, U.S.
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No. 98-377

IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

Q. TODD DICKINSON,
Acting Commissioner of Patents and Trademarks,
Petitioner,

v.

MARY E. ZURKO, THOMAS A. CASEY, JR.,
MORRIE GLASSER, JUDITH S. HALL, CLIFFORD E. KAHN,
ANDREW H. MASON, PAUL D. SAWYER,
LESLIE R. KENDALL, AND STEVEN P. LIPNER,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Administrative Procedure Act bars the Court of Appeals for the Federal Circuit from applying the "clearly erroneous" standard to review fact-finding of the Patent and Trademark Office in patent appeals.

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I. THE INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a non-profit scientific and educational

[1] The parties have consented to the submission of this brief. Their letters of consent have been filed with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person or entity, other than the *amicus curiae*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

trade association representing virtually all of the major research-based pharmaceutical companies in the United States. The members of PhRMA and its Research Affiliates are listed in Appendix A. They invent, develop and market most of the prescription medicines sold in the United States and worldwide.

No other high technology industry in the United States has a greater need for stability and certainty in the U.S. patent laws than America's research-based pharmaceutical industry. In no other industry can an invention that costs so much to discover, develop and bring to market be copied so inexpensively. The United States Office of Technology Assessment estimated, for example, that the pre-tax capitalized cost of bringing a new drug to market is $359 million (in 1990 dollars).[2] That same medicine can be copied by a generic drug company for a tiny fraction of that amount, often less than $1 million.[3] It is no overstatement to say that if it were not for a well working patent system, there would be no research-based pharmaceutical industry as we know it.

With respect to no other industry, therefore, is there a greater need for uniformity and predictability in the administration of the U.S. patent laws. PhRMA submits this brief, *amicus curiae*, in support of Respondents Zurko et al. in the interest of such uniformity and predictability. Neither PhRMA nor its Members, Research Affiliates or International Affiliates have any direct stake in the outcome of this specific case.

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[2] "1997 Industry Profile," Pharmaceutical Research and Manufacturers of America, Washington, D.C., page 16 (March, 1997).

[3] "Sustaining Innovation in U.S. Pharmaceuticals," Report of the Boston Consulting Group, page 15 (January, 1996).

II. SUMMARY OF ARGUMENT

For the reasons set forth below, PhRMA, as *amicus curiae*, urges the Court not to change the long-standing "clearly erroneous" standard of review for findings of fact by the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences.

The Administrative Procedure Act ("APA")[4] was enacted by Congress and signed by President Truman in 1946 to establish closer judicial supervision over administrative agencies that had been established during the 1930's and 1940's.[5] To construe the APA at this late date to provide greater leeway to a 150-year-old agency already subject to a long-standing and well defined standard of review is not required by that Act.[6] Overruling more than six decades of *stare decisis* on the standard of review of PTO decisions at this late date — based upon a very recent interpretation of a statute that itself was enacted more than one-half century ago and without any practical or public policy justification — would inject a serious note of uncertainty into patent law and run directly counter to the overriding reasons that the Federal Circuit was established.

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[4] 5 U.S.C. §§551-559 and 701-706.

[5] 92 Cong. Rec. 2149-50 and 2163-64 (1946), Attorney General's Manual on the Administrative Procedure Act 101 (1947).

[6] Based upon the comprehensive review by the Federal Circuit in this case — of both the history of the APA and that of the patent appeal process — the less deferential "clearly erroneous" standard of review of PTO fact-finding is an "additional requirement" under §559 of the APA recognized before the enactment of the APA.

III. ARGUMENT

The Court of Appeals for the Federal Circuit was established in 1982 in a bipartisan effort to bring certainty and stability to U.S. patent law. Based upon a key recommendation of President Carter's Domestic Review of Industrial Innovation, a centralized national court with exclusive appellate jurisdiction over patent-related cases was viewed in that Review as "a vehicle for ensuring a more uniform interpretation of the patent laws and thus contributing meaningfully and positively to predicting the strength of patents."[7] While the bill was pending it enjoyed the strong support of the Reagan Administration. As pointed out in the Report of the Senate Judiciary Committee accompanying the Federal Courts Improvement Act, "throughout the development of this legislation, the Committee and its staff have worked closely with the Departments of Justice and Commerce . . . ."[8] Then-Secretary of Commerce, the late Malcolm Baldridge, was a strong supporter of the creation of the Court. In his often-expressed view, successful business executives are able to "manage around" adversity; they cannot handle uncertainty. The research-based pharmaceutical industry also strongly supported enactment of the bill creating the Federal Circuit to help ensure uniformity and

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[7] Hearings on H.R. 6033, H.R. 6934, H.R. 3806 and H.R. 2414 before the Subcommittee on Courts, Civil Liberties and the Administration of Justice, House Committee on the Judiciary, page 797, 96th Cong., 2d Sess. (1980).

[8] Senate Report No. 97-275, page 4, 97th Cong., 1st Sess. (November 1981). The author of this brief served as Commissioner of Patents and Trademarks (1981-1985) and was directly involved in supporting the establishment of the Court of Appeals for the Federal Circuit. *See* Chisum et al., Principles of Patent Law 29 (Foundation Press 1998).

predictability in the patent law and to "eliminate geography-dependent patent opinions."[9]

Although a direct causal relationship cannot be proven, PhRMA submits that it is not coincidental that, since the creation of the Federal Circuit, America's research-based pharmaceutical industry has increased its investment in domestic research and development exponentially — from $2.3 billion in 1982 to an estimated $17 billion in 1998.[10] During that same time, the percentage of domestic sales and exports devoted to research and development has increased from 14% in 1982 to 20% in 1998.[11]

The quintessential reason for giving the Federal Circuit exclusive jurisdiction over all patent-related cases was to ensure that a single reviewing court would decide (1) which inventions would be entitled to a patent in appeals from decisions of the PTO and (2) under what rules those patents should be adjudicated in patent infringement actions in the Federal district courts. Establishing a different standard of review for fact finding by the PTO and fact finding by the district courts would run directly counter to this well conceived Congressional plan.

An inventor dissatisfied with a decision of the PTO Board of Appeals and Interferences has two alternative appeal options: (1) to file a civil action against the Commissioner in the District Court for the District of Columbia under 35 U.S.C. §145, with the possibility of a subsequent appeal from

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[9] Statement of Dr. P. Roy Vagelos, then-President, Merck, Sharp & Dohme Research Laboratories, Hearings on H.R. 6033, H.R. 6934, H.R. 3806 and H.R. 2414, *supra* note 7, at page 72.

[10] *See* Appendix B.

[11] *See* Appendix C.

the District Court to the Court of Appeals for the Federal Circuit or (2) to appeal directly to the Court of Appeals for the Federal Circuit. An applicant wishing to present factual evidence would select option (1). But if the District Court for the District of Columbia were to reverse the PTO under 35 U.S.C. §145, *its* findings of fact would be subject to a clearly erroneous standard if the PTO chose to perfect an appeal to the Federal Circuit. Would the PTO then argue that its *original* (*i.e.*, the PTO's) findings of fact be reviewed under the APA? And what standard would the District Court be asked to use in a §145 action?

Adopting the urgings of the Government at this late date — and reversing several decades of *stare decisis* — would be justified *only* for a most compelling policy or practical reason.[12] But no such reason has been argued. Indeed, PhRMA submits that no such reason exists. To the contrary, sound public policy would dictate that an inventor *not* be denied a U.S. patent based on PTO findings of fact that the Federal Circuit determines are clearly erroneous. That, however, would be the inevitable result of accepting the Government's argument.

Significantly, Congress codified the patent laws in Title 35 of the United States Code in 1952 — just six years after enactment of the APA — and in doing so Congress did *not* change the then-long-standing standard of review. Equally significant, Congress amended Title 35 in 1962 to apply the APA standard of review to the PTO, but *only* to subsection (c) of §135 regarding patent interferences — leaving standing the well-established "clearly erroneous" standard of review under 35 U.S.C. §§141 *et seq*. in patent appeals. This appears to be

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[12] *Arizona v. Rumsey*, 467 U.S. 203, 104 S. Ct. 2305, 81 L.Ed.2d 164 (1984); *Patterson v. McLean Credit Union*, 491 U.S. 164, 109 S. Ct. 2363, 105 L.Ed.2d 132 (1989).

a persuasive indication that Congress did not deem the APA applicable to any other section of Title 35 or to Title 35 in its entirety. Indeed, it was not until 1993 — more than 45 years after the APA was enacted — that the PTO itself argued that its findings of fact were somehow entitled to greater deference than they had received for more than six decades.[13]

Perhaps a key reason for that long period of acquiescence is that patent procedures at the PTO bear little resemblance to what is normally viewed as administrative fact-finding. A Patent Examiner reviews a submitted patent application against "prior art" — *i.e.*, prior published patents and publications — and makes an *ex parte* determination of patentability, typically under 35 U.S.C. §§101, 102, 103 and 112. Appellate review by the PTO's Board of Appeals and Interferences does not involve administrative fact finding but only the submission of written and possibly unrecorded oral arguments. The "facts" are nearly always limited to the patent application itself and the published prior art — no more![14] This is sharp contrast to normal administrative fact finding under the APA that involves the presentation of factual or expert testimony or evidence. The "unsupported by substantial evidence" test of the APA makes little sense with respect to PTO appeals. It could be argued that the

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[13] *See In re Napier*, 55 F.3d 610, 34 USPQ2d 1782 (Fed. Cir. 1995), wherein the Commissioner of Patents and Trademarks appears for the first time to argue that the APA's standards of review should be applied to PTO's findings of fact on patentability.

[14] *See generally*, Manual of Patent Examining Procedure, Chapter 1200 (U.S. Patent and Trademark Office, 7th ed. 1998). The author of this brief also served as a Patent Examiner (1957-1961) and as Deputy General Counsel of the National Aeronautics and Space Administration (1976-1981). In that latter position, he supervised NASA's participation in a myriad of administrative hearings, each fundamentally different from the "fact finding" of PTO patent appeals.

Examiner's judgment or opinion that an invention is obvious under 35 U.S.C. §103 — *e.g.*, on the issue of his or her using impermissible hindsight — would nearly always be supported by "substantial evidence" (*i.e.*, the published prior art) even if that judgment or opinion were deemed to be clearly erroneous by a reviewing court.

IV. CONCLUSION

The long-established "clearly erroneous" standard of review used for decades is ideally suited to the virtually unique administrative procedures used by the PTO in determining issues of patentability. The APA does not require a change in that standard. Nor should more than six decades of *stare decisis* be overturned without any practical or public policy justification.

For the foregoing reasons, PhRMA urges this Court to affirm the decision of the Federal Circuit in this case.

Respectfully submitted,

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Dated: January 14, 1999

APPENDIX -

APPENDIX A

Pharmaceutical Research and Manufacturers of America

PhRMA MEMBER COMPANIES
JANUARY 1999

MEMBERS

Agouron Pharmaceuticals
Aiza Copporation
American Home Products, Corp.
Amgen, Inc.
Astra Pharmaceuticals
Athena Neurosciences, Inc.
Bayer Corporation
Biogen, Inc.
Boehringer Ingelheim Corporation
Bristol-Myers Squibb Company
Dupont Pharmaceuticals
Fujisawa USA, Inc.
Genentech, Inc.
Genzyme Corporation
Gilead Sciences
Glaxo Wellcome Inc.
Hoechst Marion Roussel
Hoffman-La Roche, Inc.
Johnson & Johnson
Knoll Pharmaceutical Company
Eli Lilly and Company
The Liposome Company, Inc.
Merck & Co., Inc.
Novartis Pharmaceuticals Corp.
Nycomed Inc.
Organon Inc.
Pasteur Merieux Connaught
Pfizer Inc.
Pharmacia & Upjohn
The Procter & Gamble Company
Purdue Pharm L.P.
Rhone-Poulenc Rorer, Inc.
Sanofi Pharmaceuticals, Inc.
Scherring-Plough Corporation
Schwarz Pharma Inc.
Searle
Serono Laboratories, Inc.
SmithKline Beecham p.l.c.
Solvay Pharmaceuticals, Inc.
3M Pharmaceuticals
Warner-Lambert Company
Zeneca Pharmaceuticals Group

RESEARCH AFFILIATES

Affymax Research Institute
Alkermes, Inc.
Aronex Pharmaceuticals, Inc.
Astra Arcus USA
Aviron
Axys Pharmaceuticals, Inc.
Beacon Laboratories, Inc.
Block Drug Company, Inc.
Cambridge NeuroScience, Inc.
Celgene Corporation
Cephalon, Inc.
Covance, Inc.
Cyto Therapeutics, Inc.
ICOS Corporation
ISIS Pharmaceuticals, Inc.
Ligand Pharmaceuticals, Inc.
North American Vaccine, Inc.
PathoGenesis Corporation
Penwest Pharmaceuticals Group
Scios Inc.
Sepracor, Inc.
TheraTech, Inc.
Vertex Pharmaceuticals, Inc.
ViroTex Corporation

APPENDIX B

Growth in Domestic U.S. R&D and R&D Abroad, Ethical Pharmaceuticals Research-based Pharmaceutical Companies, 1970-98

Year	Domestic U.S. R&D ($ mil.)	Annual Percent Change	R&D Abroad ($mil.)	Annual Percent Change	Total ($mil.)	Annual Percent Change
*1998	17,222.5	11.0%	3,839.0	9.9%	21,061.5	10.8%
*1997	15,516.6	13.9%	3,492.1	6.5%	19,008.7	12.4%
1996	13,627.1	14.8%	3,278.5	-1.6%	16,905.6	11.2%
1995	11,874.0	7.0%	3,333.5	**	15,207.4	**
1994	11,101.6	6.0%	2,347.8	3.8%	13,449.4	5.6%
1993	10,477.1	12.5%	2,262.9	5.0%	12,740.0	11.1%
1992	9,312.1	17.4%	2,155.8	21.3%	11,467.9	18.2%
1991	7,928.6	16.5%	1,776.8	9.9%	9,705.4	15.3%
1990	6,802.9	13.0%	1,617.4	23.6%	8,420.3	14.9%
1989	6,021.4	15.0%	1,308.6	0.4%	7,330.0	12.1%
1988	5,233.9	16.2%	1,303.6	30.6%	6,537.5	18.8%
1987	4,504.1	16.2%	998.1	15.4%	5,502.2	16.1%
1986	3,875.0	14.7%	865.1	23.8%	4,740.1	16.2%
1985	3,378.7	13.3%	698.9	17.2%	4,077.6	13.9%
1984	2,982.4	11.6%	596.4	9.2%	3,578.8	11.2%
1983	2,671.3	17.7%	546.3	8.2%	3,217.6	16.0%
1982	2,268.7	21.3%	505.0	7.7%	2,773.7	18.6%
1981	1,870.4	20.7%	469.1	9.7%	2,339.5	18.4%
1980	1,549.2	16.7%	427.5	42.8%	1,976.7	21.5%
1979	1,327.4	13.8%	299.4	25.9%	1,626.8	15.9%
1978	1,166.1	9.7%	237.9	11.6%	1,404.0	10.0%
1977	1,063.0	8.1%	213.1	18.2%	1,276.1	9.7%
1976	983.4	8.8%	180.3	14.1%	1,163.7	9.6%
1975	903.5	13.9%	158.0	7.0%	1,061.5	12.8%
1974	793.1	12.0%	147.7	26.3%	940.8	14.0%
1973	708.1	8.1%	116.9	64.0%	825.0	13.6%
1972	654.8	4.5%	71.3	24.9%	726.1	6.2%
1971	626.7	10.7%	57.1	9.2%	683.8	10.6%
1970	566.2	—	52.3	—	618.5	—

* Estimated

** R&D Abroad affected by merger and acquisition activity.

Note: Data for 1996, 1997 and 1998 revised as of 6/98 from previously published data. R&D expenditures for ethical pharmaceuticals only. Domestic U.S. R&D includes expenditures within the United States by research-based pharmaceutical companies. R&D Abroad includes expenditures outside the United States by U.S.-owned research-based pharmaceutical companies. Numbers may not add exactly due to rounding.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 1998.

APPENDIX C

R&D as a Percent of U.S. Sales, Ethical Pharmaceuticals, Research-based Pharmaceutical Companies, 1970-1998

Year	Company-financed Domestic U.S. R&D ($mil.)	Domestic U.S. Sales ($mil.)	U.S. Exports ($mil.)	R&D as a % of Sales + Exports
*1998	17,157.7	81,289.2	4,462.0	20.0%
*1997	15,422.0	71,761.9	4,025.9	20.3%
1996	13,576.4	64,741.4	3,794.4	19.8%
1995	11,833.9	57,145.5	3,993.3	19.4%
1994	11,100.8	50,740.4	3,606.1	20.4%
1993	10,473.0	48,590.9	3,982.7	19.9%
1992	9,309.1	48,095.5	4,042.7	17.9%
1991	7,923.6	44,304.5	3,523.5	16.6%
1990	6,800.1	38,486.7	3,420.6	16.2%
1989	6,019.3	32,706.6	3,145.8	16.8%
1988	5,228.7	28,582.6	2,696.2	16.7%
1987	4,503.2	25,879.1	2,013.3	16.1%
1986	3,870.9	23,658.8	2,044.2	15.1%
1985	3,370.7	20,742.5	1,556.9	15.1%
1984	2,976.4	19,026.1	1,340.8	14.6%
1983	2,663.1	16,805.0	1,335.7	14.7%
1982	2,265.6	14,743.9	1,446.3	14.0%
1981	1,866.2	12,665.0	1,393.8	13.3%
1980	1,544.1	11,788.6	1,219.3	11.9%
1979	1,319.8	10,651.3	1,154.8	11.2%
1978	1,159.1	9,580.5	1,064.7	10.9%
1977	1,053.0	8,550.4	947.6	11.1%
1976	973.6	7,951.0	894.8	11.0%
1975	894.5	7,135.7	753.7	11.3%
1974	784.5	6,470.4	734.0	10.9%
1973	697.5	5,686.5	565.6	11.2%
1972	648.0	5,210.1	377.9	11.6%
1971	619.6	5,144.9	382.4	11.2%
1970	558.6	4,552.5	344.1	11.4%

* estimated

Notes:
1. R&D figures for 1996, 1997 and 1998 revised as of 6/98 from previously published data.
2. Ethical pharmaceuticals only. R&D Basis: Intramural and extramural company-financed Domestic U.S. R&D expenditures for human-use and veterinary-use pharmaceuticals.
3. Sales Basis: Reporting basis is net domestic U.S. Sales plus U.S. Exports (includes exports to other firms as well as intrafirm exports.

Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 1998.